

REMARKS

Claims 1-6, 8-11, 13-14, 16-17, 19-26, and 28-29 are pending in this application. Claims 7, 12, 15, 18, 27, and 30-31 have been canceled without prejudice. Claims 1-2, 4-5, 8-10, 13, 16-17, 19-22, 24, and 26 are amended by this Reply. The specification has been amended at the paragraphs beginning at page 7, line 8; page 8, line 12; page 8, line 17; page 8, line 22; page 9, line 21; and the tables following Examples 1-6. These amendments introduce no new matter into the application.

Double Patenting Rejection

The Action provisionally rejected claims 1-3, 5, 6, 8, 9, 16, 17, and 21 under the doctrine of nonstatutory obviousness-type double patenting over claims 30, 37, 39, and 40 of copending Application No. 10/495,961. Applicant notes that the claims in both applications are under additional rejections above the double patenting rejection. Once all of the set rejections have been obviated in at least one of the applications, applicant will consider whether a terminal disclaimer is appropriate.

Claim Rejections – 35 USC §112, 2nd Paragraph

Claims 6 and 8

The Action maintained the rejection of claims 6 and 8 under 35 U.S.C. §112, second paragraph, for inclusion of numbers relating to trademarked products. These claims were previously amended to remove the trademarked term “Carbopol”

and instead recite “carbomer 971P” and “carbomer 974P.” The Action maintained the prior rejections, stating that the numbers relate to different trademarked products, and determination of the properties of the polymer still relies in part on the trademarked names. In response, Applicant has amended the Application throughout to replace all references to “Carbopol 971P” and “Carbopol 974P,” with “carbomer 971P” and “carbomer 974P.” Applicant submits that each of these terms is generic and that the numbers indicate grades used by a variety of suppliers to indicate carbomers having similar properties. See, for example, <http://www.corelpharmachem.com/acrypol.htm> (Products include carbomers under the trade names ACRYPOL 971, ACRYPOL 971P, ARCYPOL 974 and ACRYPOL 974P); <http://www.carbomers.com/carbomer.htm> (Products include carbomers under the trade names KADPOL 971P and KADPOL 974); and <http://www.librawpharma.in/carbomer-934p-974p.html> (Carbomers sold under generic names carbomer 974P and carbomer 971), copies enclosed. Withdrawal of the rejections of claims 6 and 8 under 35 U.S.C. §112, second paragraph is respectfully requested.

Claim 22

The Action maintained the rejection of claim 22 under 35 U.S.C. §112, second paragraph, for failing to define the claim language “substantially the same.” Claim 22 has been amended to remove this language, and instead recite “the composition

having a C_{max} within 80-120% of a single dose....” This amendment is supported by the original specification, which states “In fact, the C_{max} values were within the 80-120% confidence interval recommended by the US FDA,” at page 17, lines 17-16. A person of ordinary skill in the art would recognize this portion of the specification to mean that the C_{max} values of the claimed composition were within 80-120% of that of a single dose. Withdrawal of the rejection of claim 22 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim 8

The Action further rejected claim 8 under 35 U.S.C. §112, second paragraph for its dependency from a canceled base claim. Claim 8 has amended to obviate this rejection. Withdrawal of the rejection of claim 8 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim Rejections – 35 U.S.C. §103(a)

Kshirsagar

The Action rejected claims 1-6, 8-11, 13, 14, 16, 17, 19-26, and 28 under 35 U.S.C. §103(a) as obvious over Kshirsagar (WO 04/019901). Applicants respectfully traverse this rejection.

Kshirsagar fails to disclose that the concentration of carbomers range from about 5% to about 50% by weight of controlled release composition, as each of independent claims 1, 19, 21, 22, 24 and 26 has been amended to require, reciting:

“said carbomers are present at a concentration from about 5% to about 50% by weight of the composition,” (claims 1, 19, and 21);

“a combination of at least two carbomers at a concentration ranging from 5% to 50% by weight of the composition,” (claim 22);

“combination of at least two carbomers which are present at a concentration from about 5% to about 50% by weight of the controlled release composition” (claim 24); and

“about 5%-50 % by weight of at least two carbomers,” (claim 26).

These amendments are supported by the original specification at claim 10.

The Action cites Kshirsagar at page 12, lines 4-6 as teaching the claimed percentage of carbomers. This portion of Kshirsagar's disclosure teaches using 1% to 35% polymer by weight of the composition, and does not cover Applicant's claimed range of 5%-50%. In fact, each of Kshirsagar's examples discloses a composition containing either a percentage of carbomer below Applicant's claimed range, or none at all. See Examples 2-6, disclosing carbomers ranging from 0.27% to 1.07%, and Examples 1 and 7-19, disclosing no carbomers. Furthermore, none of the Examples disclose “at least two carbomers,” as each of these claims requires.

Applicant's claimed composition is advantageous over Kshirsagar's because, as shown in the Examples in the specification, the release of the drug is greatly accelerated where a lower percentage of the mixture of carbomers is used. Additionally, the advantages of using two or more carbomers are evident by comparing Applicant's Examples, in which a minimum of five hours, and up to ten or more hours elapsed prior to at least 80% of the drug being released, whereas Kshirsagar's Examples show at least 80% drug release in less than four hours. Applicant's claimed composition constitutes a substantial, nonobvious improvement over Kshirsagar's, requiring not only a change in percentage of carbomers, but also a combination of two or more carbomers in order to obtain these advantages.

Furthermore, it would not have been obvious to a person of ordinary skill in the art to modify Kshirsagar's disclosed composition as recited in Applicant's claims in order to achieve the advantages discussed above, because Kshirsagar teaches the use of carbomers as integrity enhancers, while Applicant's carbomers are used to provide sustained release of the composition. Kshirsagar actually teaches the use of Nvinyl-2-pyrrolidone/vinyl acetate copolymer, carageenan, and sodium chloride or lactose to provide sustained release properties. See Kshirsagar at p. 16, lines 15-28. A person of ordinary skill in the art would therefore have no motivation to modify the percentage of carbomer in Kshirsagar's composition to improve the sustained release properties.

Accordingly, withdrawal of the rejection of claims 1-6, 8-11, 13, 14, 16, 17, 19-26, and 28 under 35 U.S.C. §103(a) is respectfully requested.

Katzhendler and Mayron

The Action went on to reject claims 1-6, 8, 9, 13, 14, 16, 17, 19-26, and 28 under 35 U.S.C. §103(a) as obvious over Katzhendler (U.S. 6,399,086) in view of Mayron (U.S. 3,074,852). Applicants respectfully traverse this rejection.

Neither of the cited references teaches a composition including a mixture of at least two carbomers at a concentration of 5% to 50% by weight. The Action cites Example 2 of Katzhendler as teaching a mixture of carbomers. However, since Katzhendler never even mentions the use of carbomers, Applicant presumes that the Examiner refers to Example 2 of Mayron, which teaches a mixture of Carbopol 940 and 941. Mayron, however, fails to teach a mixture of two or more carbomers at a concentration of 5% to 50%, as each of the independent claims require. Mayron's Example 2, the only example utilizing two carbomers, discloses each of the carbomers in an amount of 44.5 mg, totaling 89 mg of a mixture of carbomers, and 11 mg of other ingredients, such that the mixture of carbomers makes up 89% of the weight of the composition. Mayron's mixture of carbomers is therefore well out of Applicant's claimed range, and nothing in the reference suggests producing a composition containing 5% to 50% of a mixture of carbomers.

Katzhendler fails to remedy the deficiencies of Mayron because, as discussed above, this reference fails to disclose the use of carbomers at all.

Accordingly, withdrawal of the rejection of claims 1-6, 8, 9, 13, 14, 16, 17, 19-16, and 28 under 35 U.S.C. §103(a) is respectfully requested.

Katzhendler, Mayron and Patel

The Action further rejected claims 1, 10, 11, and 28 over Katzhendler in view of Mayron, and further in view of Patel (U.S. 6,248,363). Applicant respectfully traverses this rejection.

Each of these claims should be patentable over Katzhendler and Mayron for at least the reasons discussed above. Patel also fails to teach a composition comprising at least two carbomers, and therefore fails to remedy the deficiencies of Katzhendler and Mayron.

Accordingly, withdrawal of the rejection of claims 1, 10, 11, and 28 under 35 U.S.C. §103(a) is respectfully requested.

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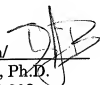
Conclusion

If the Examiner believes that any additional matters need to be addressed in order to place this application in condition for allowance, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application, including claims 1-6, 8-11, 13-14, 16-17, 19-26, and 28-29 is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

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